Amendment dated June 4, 2008
Reply to Office Action of January 4, 2008

**AMENDMENTS TO THE CLAIMS** 

Docket No.: CDSI-P01-041

1. (Currently Amended) A sustained release drug device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising an adrenergic agent and a matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent;
- (ii) a first coating on the surface of the drug core, that is substantially impermeable to the passage of the adrenergic agent, having one or more openings therein which permit diffusion of the adrenergic agent, and which is substantially insoluble and inert in body fluids and compatible with body tissues; and
- (iii) one or more additional coatings that are permeable to the passage of the adrenergic agent, and which are substantially insoluble and inert in body fluids and compatible with body tissues and comprise an adrenergic agent that is the same or different as the adrenergic agent of the inner drug core;

wherein the first and additional coatings are disposed about the inner drug core so as to produce, when implanted, a substantially constant rate of release of the adrenergic agent from the device.

- 2. (Currently Amended) A sustained release drug device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising:
  - (i) an inner drug core comprising an adrenergic agent and a matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent;
  - (ii) a first coating on the surface of the drug core, that is substantially impermeable to the passage of the adrenergic agent, having one or more openings therein which permit diffusion of the adrenergic agent, and which is substantially insoluble and inert in body fluids and compatible with body tissues; and
  - (iii) one or more additional coatings that are permeable to the passage of the adrenergic agent, and which are substantially insoluble and inert in body fluids and compatible

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with body tissues and comprise an adrenergic agent that is the same or different as

the adrenergic agent of the inner drug core;

wherein the impermeable coating has sufficient dimensional stability to be filled with an

adrenergic agent core without changing its shape.

3. (Original) The device of claim 1, wherein the impermeable coating has sufficient

dimensional stability to be filled with an adrenergic agent core without changing its shape.

4. (Withdrawn) A method for administering an adrenergic agent to the ciliary body

of an eye, the method comprising implanting a sustained-release device in or adjacent to the eye,

whereby the device delivers the adrenergic agent to the ciliary body of the eye, wherein the

adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective

concentration for a period of at least 30 days.

5. (Withdrawn) A method for administering an adrenergic agent to the ciliary body

of an eye, the method comprising implanting a sustained-release device according to any one of

claims 1 - 3 or claim 14 in or adjacent to the eye, whereby the device delivers the adrenergic

agent to the ciliary body of the eye, wherein the adrenergic agent concentration in the ciliary

body is maintained at a therapeutically effective concentration for a period of at least 30 days.

6. (Withdrawn) The method of claim 4, wherein the adrenergic agent concentration

in the ciliary body is maintained at a therapeutically effective concentration for a period of at

least 180 days.

7. (Withdrawn) The method of claim 5, wherein the adrenergic agent concentration

in the ciliary body is maintained at a therapeutically effective concentration for a period of at

least 180 days.

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8. (Withdrawn) The method of claim 4, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 360 days.

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- 9. (Withdrawn) The method of claim 5, wherein the adrenergic agent concentration in the ciliary body is maintained at a therapeutically effective concentration for a period of at least 360 days.
- 10. (Currently Amended) The device according to any one of claims 1-3 or 14, 4, 6, and 8, wherein the adrenergic agent is selected from brimonidine, [[a]]apraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunalol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.
- 11. (Withdrawn, Currently Amended) The method according to claim 5, wherein the adrenergic agent is selected from brimonidine, [[a]]apraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunalol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.
- 12. (Withdrawn, Currently Amended) The method according to claim 7, wherein the adrenergic agent is selected from brimonidine, [[a]]apraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunalol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.
- 13. (Withdrawn, Currently Amended) The method according to claim 9, wherein the adrenergic agent is selected from brimonidine, [[a]]apraclonidine, bunazosin, timolol, betaxolol, levobetaxolol, levobunalol, carteolol, isoprenaline, fenoterol, metipranolol, clenbuterol, epinephrine, and dipivefrin.

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14. (Currently Amended) A sustained release drug delivery device adapted for insertion in or adjacent to the eye of a patient, the drug delivery device comprising:

- (i) an inner drug core comprising at least one adrenergic agent and a matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent;
- (ii) a coating layer on the surface of the drug core that is <u>partially or</u> substantially impermeable to the passage of the at least one adrenergic agent, having one or more openings therein which permit diffusion of the adrenergic agent(s), and that is substantially insoluble and inert in body fluids and compatible with body tissues; and <u>comprises an adrenergic agent that is the same or different as the adrenergic agent of the inner drug core;</u>

wherein the coating is disposed about the inner drug core so as to produce, when inserted a substantially constant rate of release of the adrenergic agent(s) from the device.

## 15. (Cancelled)

- 16. (Original) The sustained release drug delivery device of claim 14, wherein the polymer matrix is bioerodible.
- 17. (Original) The sustained release drug delivery device of claim 14, wherein the device is formed by co-extruding the inner drug core and the coating layer.
- 18. (Currently Amended) A sustained release drug delivery device adapted for insertion in or adjacent to the eye of a patient, the drug delivery device comprising:
  - (i) an inner drug core comprising at least one adrenergic agent and a matrix material
    wherein said adrenergic agent is admixed in the matrix material to inhibit or
    prevent decomposition of the adrenergic agent;
  - (ii) a coating layer on the surface of the drug core that is partially or substantially permeable to the passage of the at least one adrenergic agent, having one or more openings therein which aid diffusion of the at least one adrenergic agent, and that is

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substantially insoluble and inert in body fluids and compatible with body tissues; and comprises an adrenergic agent that is the same or different as the adrenergic agent of the inner drug core;

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wherein the coating is disposed about the inner drug core so as to produce, when inserted, a substantially constant rate of release of the at least one adrenergic agent from the device.

- 19. (Cancelled)
- 20. (Original) The sustained release drug delivery device of claim 18, wherein the polymer matrix is bioerodible.
- 21. (Original) The sustained release drug delivery device of claim 20, wherein the device is formed by co-extruding the inner drug core and the coating layer.